

105TH CONGRESS
1ST SESSION

H. R. 1055

To establish within the National Institutes of Health an agency to be known as the National Center for Integral Medicine, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 13, 1997

Mr. DEFazio (for himself, Mr. FILNER, Mr. SANDERS, Ms. NORTON, Mr. MORAN of Virginia, Mr. ARCHER, Mr. ANDREWS, Mrs. MINK of Hawaii, Mr. FALCOMA, Ms. WOOLSEY, Mr. GREEN, Mr. RUSH, Mr. McDERMOTT, Mr. HINCHEY, Mr. EVANS, and Mr. FOGLIETTA) introduced the following bill; which was referred to the Committee on Commerce

A BILL

To establish within the National Institutes of Health an agency to be known as the National Center for Integral Medicine, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “National Center for
5 Integral Medicine Establishment Act”.

6 **SEC. 2. FINDINGS.**

7 The Congress finds as follows:

1 (1) From 60 to 90 percent of chronic diseases
2 may be largely prevented or treated by addressing
3 lifestyle-related issues and using medical interven-
4 tions that stimulate and support natural healing
5 processes.

6 (2) Behavioral, nutritional, preventive, and al-
7 ternative medical approaches to disease prevention
8 and treatment that emphasize these processes offer
9 a possible solution to the successful management of
10 many of our most devastating and costly chronic dis-
11 eases.

12 (3) Interventions to address chronic diseases
13 must involve the integration of these behavioral, nu-
14 tritional, preventive, and alternative medical prac-
15 tices into conventional medical practices, including
16 integration into health care delivery systems in the
17 United States.

18 (4) Over $\frac{1}{3}$ of the American public and 80 per-
19 cent of the world's population make regular use of
20 such practices.

21 (5) These practices are not usually available in
22 the current conventional health care system nor eval-
23 uated in most research institutions, yet are vital for
24 the provision of optimal health care.

1 (6) A center is needed for the support and inte-
 2 gration of knowledge across all of the agencies of the
 3 National Institutes of Health and across all medical
 4 research activities pertaining to wellness and health
 5 research, rather than further specialization of knowl-
 6 edge based on the division of disease treatment cat-
 7 egories.

8 **SEC. 3. ESTABLISHMENT OF NATIONAL CENTER FOR INTE-**
 9 **GRAL MEDICINE.**

10 (a) IN GENERAL.—Title IV of the Public Health
 11 Service Act (42 U.S.C. 281 et seq.) is amended—

12 (1) in part A—

13 (A) in section 402, by striking subsection

14 (f);

15 (B) by striking section 404A; and

16 (C) by striking section 404E; and

17 (2) in part E, by amending subpart 4 to read
 18 as follows:

19 “Subpart 4—National Center for Integral Medicine

20 **“SEC. 485C. PURPOSE OF CENTER.**

21 “(a) IN GENERAL.—The general purposes of the Na-
 22 tional Center for Integral Medicine (in this subpart re-
 23 ferred to as the ‘Center’) are—

24 “(1) the conduct and support of basic and ap-
 25 plied research (including clinical research), training,

1 the dissemination of health information, and other
2 programs, including prevention programs, with re-
3 spect to identifying and evaluating alternative medi-
4 cal treatment systems and disciplines, alternative
5 medical diagnostic systems and disciplines, and the
6 modalities of such treatment and diagnostic systems
7 and disciplines; and

8 “(2) carrying out the functions specified in sec-
9 tions 485D through 485F (relating to disease pre-
10 vention, behavioral and social sciences research, and
11 dietary supplements, respectively).

12 The Center shall be headed by a director, who shall be
13 appointed by the Secretary. The Director of the Center
14 shall report directly to the Director of NIH.

15 “(b) ADVISORY COUNCIL.—The Secretary shall es-
16 tablish an advisory council for the Center in accordance
17 with section 406, except that the members of the advisory
18 council who are not ex officio members shall include one
19 or more practitioners from each of the disciplines and sys-
20 tems with which the Center is concerned, including each
21 discipline and system in which accreditation, national cer-
22 tification, or a State license is available.

23 “(c) COMPLEMENT TO CONVENTIONAL MEDICINE.—
24 In carrying out subsection (a), the Director of the Center
25 shall, as appropriate, promote the integration of alter-

1 native medical treatment and diagnostic systems and dis-
2 ciplines into the practice of conventional medicine as a
3 complement to such medicine, including the integration of
4 such systems and disciplines into health care delivery sys-
5 tems in the United States.

6 “(d) CERTAIN EVALUATION FACTORS.—In carrying
7 out subsection (a) with respect to an alternative medical
8 treatment system or discipline (including with respect to
9 particular modalities), the Director of the Center shall
10 consider the following factors:

11 “(1) The effectiveness of the system or dis-
12 cipline as a treatment for the health condition in-
13 volved, including effectiveness with respect to acute
14 cases and effectiveness with respect to chronic cases
15 (as applicable).

16 “(2) The safety of the system or discipline, in-
17 cluding any adverse effects associated with use of
18 the system or discipline.

19 “(3) The costs of the system or discipline.

20 “(4) The extent to which the system or dis-
21 cipline promotes wellness and supports inherent
22 healing processes.

23 “(5) Such other factors as the Director consid-
24 ers appropriate.

1 “(6) A comparison of the system or discipline
2 with conventional treatments for the health condi-
3 tion, which comparison shall be made in terms of the
4 factors specified in paragraphs (1) through (4) and
5 such factors as the Director may specify under para-
6 graph (5).

7 “(e) EVALUATION OF VARIOUS DISCIPLINES AND
8 SYSTEMS.—In carrying out subsection (a), the Director
9 of the Center shall identify and evaluate alternative medi-
10 cal treatment and diagnostic modalities in each of the dis-
11 ciplines and systems with which the Center is concerned,
12 including each discipline and system in which accredita-
13 tion, national certification, or a State license is available.
14 Disciplines or systems under the preceding sentence in-
15 clude acupuncture and Oriental medicine, homeopathic
16 medicine, physical manipulation therapies, chiropractic,
17 naturopathic medicine, midwifery, and such other systems
18 and disciplines as the Director of the Center determines
19 to be appropriate.

20 “(f) CERTAIN REQUIREMENTS.—The Director of the
21 Center shall conduct or support the following activities
22 with respect to alternative medical treatment and diag-
23 nostic systems and disciplines:

24 “(1) Research on outcomes.

25 “(2) Epidemiological activities.

1 “(3) Research training.

2 “(4) Health services research.

3 “(g) DATA SYSTEM; INFORMATION CLEARING-
4 HOUSE.—

5 “(1) DATA SYSTEM.—The Director of the Cen-
6 ter shall establish a data system for the collection,
7 storage, analysis, and retrieval of data relating to al-
8 ternative medical treatment and diagnostic systems
9 and disciplines.

10 “(2) CLEARINGHOUSE.—The Director of the
11 Center shall establish an information clearinghouse
12 to facilitate and enhance, through the effective dis-
13 semination of information, knowledge and under-
14 standing of alternative medical treatment and diag-
15 nostic systems and disciplines by health profes-
16 sionals, patients, industry, and the public.

17 “(h) RESEARCH CENTERS.—

18 “(1) IN GENERAL.—The Director of the Center,
19 after consultation with the advisory council for the
20 Center, may provide support for the development
21 and operation of centers to conduct research and
22 other activities described in subsection (a)(1) with
23 respect to alternative medical treatment and diag-
24 nostic systems and disciplines.

1 “(2) REQUIREMENTS.—Each center assisted
2 under paragraph (1) shall use the facilities of a sin-
3 gle entity, or be formed from a consortium of co-
4 operating entities, and shall meet such requirements
5 as may be established by the Director of the Center.
6 Each such center shall—

7 “(A) be established as an independent en-
8 tity; or

9 “(B) be established within or in affiliation
10 with an entity that conducts research or train-
11 ing described in subsection (a)(1).

12 “(3) DURATION OF SUPPORT.—Support of a
13 center under paragraph (1) may be for a period not
14 exceeding 5 years. Such period may be extended for
15 one or more additional periods not exceeding 5 years
16 if the operations of such center have been reviewed
17 by an appropriate technical and scientific peer re-
18 view group established by the Director of the Center
19 and if such group has recommended to the Director
20 that such period should be extended.

21 “(i) BIENNIAL REPORT.—The Director of the Center
22 shall prepare biennial reports on the activities carried out
23 or to be carried out by the Center, and shall submit each
24 such report to the Director of NIH for inclusion in the
25 biennial report under section 403.

1 “(j) AVAILABILITY OF RESOURCES.—After consulta-
2 tion with the Director of the Center, the Director of NIH
3 shall ensure that resources of the National Institutes of
4 Health, including clinical facilities, are sufficiently avail-
5 able for activities of the Center.

6 “(k) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this subpart, there are authorized
8 to be appropriated \$198,000,000 for fiscal year 1998, and
9 such sums as may be necessary for each of the fiscal years
10 1999 through 2002. Amounts appropriated under this
11 subsection for fiscal year 1998 are available for obligation
12 through September 30, 2000. Amounts appropriated
13 under this subsection for fiscal year 1999 are available
14 for obligation through September 30, 2000.

15 **“SEC. 485D. OFFICE OF DISEASE PREVENTION.**

16 “(a) IN GENERAL.—There is established within the
17 Center an office to be known as the Office of Disease Pre-
18 vention (in this section referred to as the ‘Office’). The
19 Office shall be headed by a director, who shall be ap-
20 pointed by the Director of the Center. The Director of the
21 Center shall carry out the functions specified in this sec-
22 tion acting through the Director of the Office.

23 “(b) DUTIES.—

24 “(1) IN GENERAL.—The Director of the Office
25 shall promote the disease prevention research pro-

1 grams of the national research institutes, and shall
2 provide for the coordination of such programs
3 among the national research institutes and between
4 the national research institutes and other public and
5 private entities, including elementary, secondary,
6 and postsecondary schools.

7 “(2) CERTAIN DUTIES.—The Director of the
8 Office shall—

9 “(A) annually review the efficacy of exist-
10 ing policies and techniques used by the national
11 research institutes to disseminate the results of
12 disease prevention and behavioral research pro-
13 grams; and

14 “(B) recommend, coordinate, and oversee
15 the modification or reconstruction of such poli-
16 cies and techniques to ensure maximum dis-
17 semination, using advanced technologies to the
18 maximum extent practicable, of research results
19 to such entities.

20 “(c) BIENNIAL REPORT.—The Director of the Office
21 shall prepare biennial reports on the activities carried out
22 or to be carried out by the Office, and shall submit each
23 such report to the Director of the Center for inclusion in
24 the biennial report under section 485C(i). Each such re-
25 port shall include—

1 “(1) a summary of the Director’s review of ex-
2 isting dissemination policies and techniques together
3 with a detailed statement concerning any modifica-
4 tion or restructuring, or recommendations for modi-
5 fication or restructuring, of such policies and tech-
6 niques; and

7 “(2) a detailed statement of the expenditures
8 made for the prevention and dissemination activities
9 reported on and the personnel used in connection
10 with such activities.

11 **“SEC. 485E. OFFICE OF BEHAVIORAL AND SOCIAL**
12 **SCIENCES RESEARCH.**

13 “(a) IN GENERAL.—There is established within the
14 Center an office to be known as the Office of Behavioral
15 and Social Sciences Research (in this section referred to
16 as the ‘Office’). The Office shall be headed by a director,
17 who shall be appointed by the Director of the Center. The
18 Director of the Center shall carry out the functions speci-
19 fied in this section acting through the Director of the Of-
20 fice.

21 “(b) DUTIES.—

22 “(1) IN GENERAL.—With respect to research on
23 the relationship between human behavior and the de-
24 velopment, treatment, and prevention of medical
25 conditions, the Director of the Office shall—

1 “(A) coordinate research conducted or sup-
2 ported by the agencies of the National Insti-
3 tutes of Health; and

4 “(B) identify projects of behavioral and so-
5 cial sciences research that should be conducted
6 or supported by the national research institutes,
7 and develop such projects in cooperation with
8 such institutes.

9 “(2) CERTAIN DUTIES.—Research authorized
10 under paragraph (1) includes research on teen preg-
11 nancy, infant mortality, violent behavior, suicide,
12 and homelessness. Such research does not include
13 neurobiological research, or research in which the
14 behavior of an organism is observed for the purpose
15 of determining activity at the cellular or molecular
16 level.

17 “(c) BIENNIAL REPORT.—The Director of the Office
18 shall prepare biennial reports on the activities carried out
19 or to be carried out by the Office, and shall submit each
20 such report to the Director of the Center for inclusion in
21 the biennial report under section 485C(i).

22 **SEC. 485F. OFFICE OF DIETARY SUPPLEMENTS.**

23 “(a) IN GENERAL.—There is established within the
24 Center an office to be known as the Office of Dietary Sup-
25 plements (in this section referred to as the ‘Office’). The

1 Office shall be headed by a director, who shall be ap-
2 pointed by the Director of the Center. The Director of the
3 Center shall carry out the functions specified in this sec-
4 tion acting through the Director of the Office.

5 “(b) DUTIES.—

6 “(1) IN GENERAL.—The Director of the Office
7 shall—

8 “(A) expand the activities of the national
9 research institutes with respect to the potential
10 role of dietary supplements as a significant part
11 of the efforts of the United States to improve
12 health care; and

13 “(B) promote scientific study of the bene-
14 fits of dietary supplements in maintaining
15 health and preventing chronic disease and other
16 health-related conditions.

17 “(2) CERTAIN DUTIES.—The Director of the
18 Office shall—

19 “(A) conduct and coordinate scientific re-
20 search within the National Institutes of Health
21 relating to dietary supplements and the extent
22 to which the use of dietary supplements can
23 limit or reduce the risk of diseases such as
24 heart disease, cancer, birth defects,
25 osteoporosis, cataracts, or prostatism;

1 “(B) collect and compile the results of sci-
2 entific research relating to dietary supplements,
3 including scientific data from foreign sources or
4 other offices of the Center;

5 “(C) serve as the principal advisor to the
6 Secretary and to the Assistant Secretary for
7 Health and provide advice to the Director of
8 NIH, the Director of the Centers for Disease
9 Control and Prevention, and the Commissioner
10 of Food and Drugs on issues relating to dietary
11 supplements including—

12 “(i) dietary intake regulations;

13 “(ii) the safety of dietary supple-
14 ments;

15 “(iii) claims characterizing the rela-
16 tionship between dietary supplements and
17 the prevention of disease or other health-
18 related conditions;

19 “(iv) claims characterizing the rela-
20 tionship between dietary supplements and
21 the maintenance of health; and

22 “(v) scientific issues arising in connec-
23 tion with the labeling and composition of
24 dietary supplements;

1 “(D) compile a database of scientific re-
2 search on dietary supplements and individual
3 nutrients; and

4 “(E) coordinate funding relating to dietary
5 supplements for the National Institutes of
6 Health.

7 “(c) BIENNIAL REPORT.—The Director of the Office
8 shall prepare biennial reports on the activities carried out
9 or to be carried out by the Office, and shall submit each
10 such report to the Director of the Center for inclusion in
11 the biennial report under section 485C(i).

12 “(d) DEFINITION.—For purposes of this section, the
13 term ‘dietary supplement’ has the meaning given such
14 term in section 201(ff) of the Federal Food, Drug, and
15 Cosmetic Act.”.

16 (b) TECHNICAL AND CONFORMING AMENDMENTS.—
17 Part A of title IV of the Public Health Service Act (42
18 U.S.C. 281 et seq.), as amended by subsection (a) of this
19 section, is amended—

20 (1) in section 401(b)(2), by amending subpara-
21 graph (E) to read as follows:

22 “(E) The National Center for Integral Medi-
23 cine.”;

1 (2) in section 402, by redesignating subsections
2 (g) through (k) as subsections (f) through (j), re-
3 spectively; and

4 (3) by redesignating sections 404B through
5 404D as sections 404A through 404C, respectively.

6 **SEC. 4. SAVINGS PROVISIONS.**

7 All officers and employees employed in the Office of
8 Alternative Medicine on the day before the date of the en-
9 actment of this Act (pursuant to section 404E of the Pub-
10 lic Health Service Act, as in effect on such day) are trans-
11 ferred to the National Center for Integral Medicine, in-
12 cluding the members and staff of the advisory council, and
13 there are transferred to such Center all funds of such Of-
14 fice available on such day and all other legal rights and
15 duties of such Office. With respect to the establishment
16 of a designated Center office pursuant to the amendments
17 made by section 3, such establishment shall be construed
18 to constitute a transfer of the designated Center office to
19 the National Center for Integral Medicine from the Office
20 of the Director of the National Institutes of Health (in
21 which the designated Center office was located pursuant
22 to the relevant former section of the Public Health Service
23 Act). A transfer referred to in the preceding provisions
24 of this section does not affect the status of any of the
25 officers or employees involved (except to the extent that

1 the amendments made by section 3 affect the authority
2 to make appointments to employment positions); does not
3 affect the availability of the funds for the purposes for
4 which the funds were appropriated (except that in the case
5 of such National Center such purposes shall apply with
6 respect to the National Center to the same extent and in
7 the same manner as the purposes applied with respect to
8 the Office of Alternative Medicine); and does affect any
9 other legal rights and duties, which continue in effect in
10 accordance with their terms. For purposes of this section:
11 (1) The term “designated Center office” means each of
12 the Office of Disease Prevention (as established in section
13 485D of the Public Health Service Act, as added by the
14 amendments made by section 3 of this Act); the Office
15 of Behavioral and Social Sciences Research (as established
16 in section 485E of such Act, as so added); and the Office
17 of Dietary Supplements (as established in section 485F
18 of such Act, as so added). (2) The term “relevant former
19 section of the Public Health Service Act”, with respect to
20 a designated Center office, means, in the case of the Office
21 of Disease Prevention, section 402(f) of the Public Health
22 Service Act as in effect on the day before the date of the
23 enactment of this Act; in the case of the Office of Behav-
24 ioral and Social Sciences Research, section 404A of such
25 Act as in effect on such day; and in the case of the Office

1 of Dietary Supplements, section 485C of such Act as in
2 effect on such day.

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